From: Wozniak, Chris [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8287E326F7A148FB9870D5D79333DEBC-CHRIS WOZNIAK]

Sent: 3/24/2017 4:55:48 PM

To: Dyer, Brian [Dyer.Brian@epa.gov]; You.In-Soon@epa.gov; Nesci, Kimberly [Nesci.Kimberly@epa.gov]; Chris Wozniak

[Wozniak.Chris@epa.gov]; Barsoum, Ibrahim [Barsoum.Ibrahim@epa.gov]; Cerrelli, Susanne

[Cerrelli.Susanne@epa.gov]; John Kough [Kough.John@epa.gov]; Gagliardi, Joel [Gagliardi.Joel@epa.gov]; Martinez, Jeannette [Martinez.Jeannette@epa.gov]; Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]; Borges, Shannon [Borges.Shannon@epa.gov]; Reynolds, Alan [Reynolds.Alan@epa.gov]; Huskey, Angela [Huskey.Angela@epa.gov]; Kaczmarek, Chris [Kaczmarek.Chris@epa.gov]; Jeannine Kausch [Kausch.Jeannine@epa.gov]; Wakefield, Benjamin J. [wakefield.benjamin@epa.gov]; Facey, Judy [Facey.Judy@epa.gov]; McNally, Robert [Mcnally.Robert@epa.gov];

Leahy, John [Leahy.John@epa.gov]; Mike Mendelsohn [Mendelsohn.Mike@epa.gov]; Carlisle, Sharon [Carlisle.Sharon@epa.gov]; Wingeart, Jennifer [Wingeart.Jennifer@epa.gov]; Djurickovic, Milutin [Djurickovic.Milutin@epa.gov]; Tapken, Wiebke [Tapken.Wiebke@epa.gov]; Eiden, Catherine [Eiden.Catherine@epa.gov]; Hathaway, Margaret [Hathaway, Margaret@epa.gov]; Hartman, Mark

[Hartman.Mark@epa.gov]; Bilardo, Elyse [Bilardo.Elyse@epa.gov]; Zuber, Mohammed

[Zuber.Mohammed@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]

CC: Adeeb, Shanta [Adeeb.Shanta@epa.gov]; Anderson, Marcia [Anderson.Marcia@epa.gov]; Anderson, Neil

[Anderson.Neil@epa.gov]; Arnold, Elyssa [Arnold.Elyssa@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov];

Backus, Byron [Backus.Byron@epa.gov]; Balan, Aswathy [Balan.Aswathy@epa.gov]; Baris, Reuben

[Baris.Reuben@epa.gov]; Benbow, Bethany [Benbow.Bethany@epa.gov]; Berwald, Derek

[Berwald.Derek@epa.gov]; Bloem, Thomas [Bloem.Thomas@epa.gov]; Chen, Carl [chen.carl@epa.gov]; Chism, William [Chism.Bill@epa.gov]; Mary Clock-Rust [Clock-Rust.Mary@epa.gov]; Cook, Colwell [cook.colwell@epa.gov];

Eiden, Catherine [Eiden.Catherine@epa.gov]; Finn, Cara [Finn.Cara@epa.gov]; Gaines, Jennifer

[gaines.jennifer@epa.gov]; Hathaway, Margaret [Hathaway.Margaret@epa.gov]; Hill.Shaunta@epa.gov; Isbell, Diane [Isbell.Diane@epa.gov]; Jones, Russell [Jones.Russell@epa.gov]; Jones, Arnet [Jones.Arnet@epa.gov]; Kaul,

Monisha [Kaul.Monisha@epa.gov]; Keltz, Colleen [Keltz.Colleen@epa.gov]; Kitchens, Bruce

[Kitchens.Bruce@epa.gov]; John Kough [Kough.John@epa.gov]; Kramer, George [Kramer.George@epa.gov];

Liccione, John [Liccione.John@epa.gov]; Lin, James [lin.james@epa.gov]; Lloyd, Matthew [Lloyd.Matthew@epa.gov];

Marchese.Jacquelyn@epa.gov; Martin, Kathleen [Martin.Kathleen@epa.gov]; McCormack, Karen [McCormack.Karen@epa.gov]; Metzger, Michael [Metzger.Michael@epa.gov]; Myers, Clayton

[Myers.Clayton@epa.gov]; Miller, Shirley [Miller.Shirley@epa.gov]; Moriarty, Thomas [Moriarty.Thomas@epa.gov]; Mostaghimi, Siroos [Mostaghimi.Siroos@epa.gov]; Murasaki, Seiichi [Murasaki,Seiichi@epa.gov]; Nguyen, Khue [Nguyen.Khue@epa.gov]; Nesci, Kimberly [Nesci.Kimberly@epa.gov]; Parrott, Patricia [parrott.patricia@epa.gov];

Petrella, Carlyn [Petrella.Carlyn@epa.gov]; Pope-Varsalona, Hannah [Pope-Varsalona.Hannah@epa.gov]; Roe,

Lindsay [Roe.Lindsay@epa.gov]; Rothman, Gabe [Rothman.Gabe@epa.gov]; Rowland, Grant

[Rowland.Grant@epa.gov]; Sahafeyan, Mohsen [Sahafeyan.Mohsen@epa.gov]; Scheltema, Christina

[Scheltema.Christina@epa.gov]; Schmid, Emily [Schmid.Emily@epa.gov]; Trujillo.Jolene@epa.gov; Waleko, Garland [Waleko.Garland@epa.gov]; Walsh, Michael [Walsh.Michael@epa.gov]; Williams.Tuere@epa.gov; Yohannes, Lia

[Yohannes.Lia@epa.gov]; Meadows, Sarah [Meadows.Sarah@epa.gov]; Becker, Jonathan

[Becker.Jonathan@epa.gov]; Dobreniecki, Sarah [Dobreniecki.Sarah@epa.gov]; Tindall, Kelly [tindall.kelly@epa.gov];

Welch, Kara [welch.kara@epa.gov]; Hawkins, Caleb [Hawkins.Caleb@epa.gov]

Subject: GE News & Science

FYI

From: Cournoyer, Patrick [mailto:Patrick.Cournoyer@fda.hhs.gov]

Sent: Friday, March 24, 2017 9:36 AM

>

Subject: GE News & Science

NEWS

Kenya's Agriculture Secretary blocks field trials with GE corn

- Researchers planned National Performance Trials with GE corn, which they expected would lead to commercialization in 2018
- While the National Biosafety Authority (NBA) was in favor of the trials, the National Environmental Management Authority (NEMA) was opposed
- The trials were presumably for Bt insect resistant corn (MON810), although conflicting reports have said the corn was drought tolerant (MON87460)

Daily Nation (Kenya): Kenya rules out open trials on genetically modified crops

European Academies' Science Advisory Council releases report on genome editing

- The report requests that EU regulators confirm that site directed mutagenesis in plants falls outside the scope of EU legislation on GMOs
- The report recommends that new technologies, "be excluded from regulation if the genetic changes they produce are similar to, or indistinguishable from, the product of conventional breeding and if no novel, product-based risk is identified."
- The report recommends the same for genome edited animals, "to regulate the trait rather than the technology and be open and explicit about what is being done."

EASAC: Genome editing: scientific opportunities, public interests and policy options in the European Union

The Target Malaria initiative is working to win community support for biotech efforts to suppress malaria in rural Burkina Faso

- The project has begun by killing mosquitoes with insecticide to enable population monitoring
- It later plans to release genome edited sterile males, and hopes one day, with the consent of the community, to test a gene drive

STAT: In a remote West African village, a revolutionary genetic experiment is on its way — if residents agree to it

New York Medical College finds no evidence that that Monsanto ghostwrote a professor's paper on glyphosate, despite last week's reporting in the *New York Times*

- Danny Hakim claimed that Monsanto ghostwrote a 2000 paper in Regulatory Toxicology and Pharmacology, which reported a lack of evidence that glyphosate harms people
- Hakim based his claims on internal Monsanto emails obtained in an ongoing court case blaming glyphosate for cancer deaths

Science: Update: After quick review, medical school says no evidence Monsanto ghostwrote professor's paper

Houston officials are talking with Oxitec about trying GE mosquitoes

ABC News: Use of genetically modified mosquitoes considered in Houston

Cargill expands offering of Non-GMO Project certified ingredients

- In October, Cargill announced it would offer non-GMO erythritol, cane sugar and high oleic sunflower oil
- Now it says it will offer Non-GMO Project certified "Stevia sweeteners, dry corn (mill, grits, flour), glucose heirloom syrup, corn syrup solids, dextrin, maltodextrin, modified food starch, native starch, mid oleic sunflower oil, Clear Valley® High Oleic Canola Oil, soybean oil, chicory inulin, and erythritol (using corn feedstock)"

Cargill: Cargill strengthens North American Non-GMO offering with Identity Preservation process, more Non-GMO Project Verified ingredients

MIT Technology Review lists five biotech products it thinks US regulators aren't ready for

- The article was inspired by the 2017 NAS report "Preparing for Future Products of Biotechnology"
- The article mentions live bacteria that act like drugs, genome edited plants and animals, cultured meat, GE fragrant moss, and gene drives

MIT Technology Review: 5 Biotech Products U.S. Regulators Aren't Ready For

Canadian growers expected to plant Simplot GE potatoes this year

Canadian approval came too late for 2016 commercial planting

• Growing the potatoes requires a contract with Simplot, which specifies that growers exclusively grow the GE potatoes to avoid unintended mixing

Grainews: GM potatoes are going in the ground

Princess Anne supports GE crops and animals, unlike her famously opposed brother, Prince Charles

- In a radio interview she said, ""I have rare breed livestock so genetic modification would be a bonus if I could just find a way of making them a little more robust in terms of survivability."
- She said she would be open to growing GE crops on her estate after Brexit

The Telegraph: Charles and Anne at odds over GM crops? Princess Royal says she would be happy to grow them on her estate

Futurism releases infographic on GE food

- Like a recent NPR article, the infographic mistakenly says cisgenic crops face fewer regulatory steps with FDA and USDA (NPR: Why The Arctic Apple Means You May Be Seeing More GMOs At The Store)
- · It includes a graphic depiction of various breeding approaches, including genome editing
- The graphic notes the gap in risk perception with GE crops between scientists and the public

Futurism: Next Gen GMOs: Future Food or Frankenfood?

Newsweek features last week's report of a GE corn variety that suppresses production of Aspergillus aflatoxin

• Regarding public acceptance, scientist Nancy Keller said, "Can people accept something like this because it's genetically engineered? ... Maybe it's better to have this new strain and not get cancer."

Newsweek: A genetically modified corn could stop a deadly fungal poison — If we let it Science Advances (original study): Aflatoxin-free transgenic maize using host-induced gene silencing

George Church's Harvard spinoff eGenesis raises capital to develop GE pigs for organ transplants

 Church's group is using CRISPR to remove virus sequences and aims to eliminate proteins that trigger immune responses in humans

MIT Technology Review: CRISPR May Speed Pig-to-Human Transplants

A reporter criticizes a dietitian for not publically disclosing partnership with Monsanto

- Dietitian Mary Lee Chin was paid by Monsanto as part of its Leaders Engaged in Advancing Dialogue (L.E.A.D.) initiative, to promote science-based discussion of GE crops and related issues on social media
- Journalists have been obtaining story leads after mining emails obtained from FOI requests directed at public sector academics and Monsanto emails obtained from a court case blaming glyphosate for cancer deaths
- The author repeats the contested claim that Monsanto ghostwrote a professor's paper on glyphosate

Mic: Leaked email reveals dietitian's murky relationship with Monsanto

Researchers use genes from drought tolerant "resurrection" plants to improve drought tolerance in crops

 Researchers at Cape Town University are testing genes in corn, beans, and teff (the grain used in the Ethiopian bread, injera)

Reuters: Could 'resurrection' crops survive drought and feed a hungry planet?

Cultured meat and lab-made milk products nearing market but face unclear regulatory path

 The article considers potential for USDA regulation as meat, FDA regulation as a food ingredient, and FDA regulation as an animal drug

Science: Artificial chicken grown from cells gets a taste test—but who will regulate it?

COMMENTARY

Epistemologist Giovanni Tagliabue creatively rebuts Jennifer Kuzma's 2016 comment piece in *Nature*, which argued that GE crop regulatory triggers should not be purely scientific

- Kuzma opposes the widely held view among scientists that the breeding method (process) is irrelevant to safety, and that regulatory triggers should instead hinge on the attributes of the new variety (product)
- Tagliabue's piece depicts a hypothetical discussion between a social scientist, an epistemologist, a food safety expert, and developers of a new pepper variety
- Tagliabue lifts text from Kuzma's 2016 piece for the social scientist's statements, which he then rebuts using invented dialogue from the other characters in the discussion
- Tagliabue's characters cite what is known as the "Stanford Model" as a recommendable science-based approach
- The "Stanford Model" was recently re-proposed here: *Nature Biotechnology:* A risk-based approach to the regulation of genetically engineered organisms
- Kuzma's original piece: Nature: Policy: Reboot the debate on genetic engineering

Life Sciences, Society and Policy: Product, not process! Explaining a basic concept in agricultural biotechnologies and food safety

SCIENCE

Review summarizes progress and future goals of HarvestPlus, a large-scale initiative to alleviate nutritional deficiencies in the developing world through crop biofortification

- The program's past successes and near-term goals involve only non-transgenic crops, because GE crops face regulatory challenges
- HarvestPlus has released more than 150 biofortified, non-transgenic varieties of 10 crops in 30 countries
- HarvestPlus has released iron-enriched bean and pearl millet; provitamin A enriched corn, cassava, and sweet potato; and zinc-enriched wheat and rice
- The program's successes earned some of its participants the 2016 World Food Prize

Global Food Security: Improving nutrition through biofortification: A review of evidence from HarvestPlus, 2003 through 2016

Scientists propose rapid domestication of crop wild relatives using genome editing to replicate alleles known to underlie domestication of well-studied crops

- As an example, they propose editing more than two dozen genes in a wild tomato relative native to the Galapagos Islands to create a new species of cultivated tomato
- They acknowledge it will be important to ensure safe levels of toxic alkaloids known to exist in tomatoes and their wild relatives
- They list several crop wild relative species that might be amenable to accelerated domestication through genome editing

Plant Science: Genome editing as a tool to achieve the crop ideotype and de novo domestication of wild relatives: Case study in tomato

Review summarizes efforts to improve micronutrient content in crops through GE

 Various GE crops have been developed for increased levels of Vitamin A, Vitamin C, zinc, iron, and other vitamins and minerals

Current Opinion in Biotechnology: GM biofortified crops: potential effects on targeting the micronutrient intake gap in human populations

Summary of "Genome Editing and the Future of Farming" meeting held at the Roslin Institute in the UK

• The meeting addressed genome editing in livestock

Transgenic Research: Genome Editing and the Future of Farming meeting report

Methionine-enriched potatoes express a cystathionine gamma-synthase from *Arabidopsis* and have silenced methionine gamma-lyase

• Potatoes are deficient in methionine, an essential amino acid

Journal of Agricultural and Food Chemistry: Concurrent overexpression of Arabidopsis cystathionine gamma-synthase and silencing of endogenous methionine gamma-lyase enhances tuber methionine content in Solanum tuberosum

Wheat lines genetically engineered to suppress gliadin levels studied for effect of nitrogen fertilizer on glutenin content

- Certain fertilization strategies affected glutenin levels
- These wheat varieties are under development by Spanish researchers and have already been evaluated for baking properties

Frontiers in Plant Science: Characterization of Changes in Gluten Proteins in Low-Gliadin Transgenic Wheat Lines in Response to Application of Different Nitrogen Regimes

Corn expressing double stranded RNA homologous to the corn borer neuropeptide F gene inhibits corn borer growth Scientific Reports: A potential and novel type transgenic corn plant for control of the Corn Borer

Sorghum expressing the wheat resistance gene Lr34 has enhanced resistance to anthracnose and rust Plant Biotechnology Journal: The wheat Lr34 multi-pathogen resistance gene confers resistance to anthracnose and rust

in sorghum

GE chrysanthemums with increased lignin restrict growth of aphids

The plants overexpress the endogenous transcription factor MYB19

International Journal of Molecular Sciences: <u>CmMYB19 Over-Expression Improves Aphid Tolerance in Chrysanthemum by</u> Promoting Lignin Synthesis

Rice developed with resistance to Rice black-streaked dwarf virus

The rice express RNA targeting the viruses S7-2 or S8 genes

Transgenic Research: RNAi-mediated resistance to rice black-streaked dwarf virus in transgenic rice

Non-target, beneficial ladybird beetle *Propylea japonica* is not adversely affected by consuming corn pollen expressing *Cry1le*

Toxins: Consumption of Bt Maize Pollen Containing Cry1le Does Not Negatively Affect Propylea japonica (Thunberg) (Coleoptera: Coccinellidae)

Review of Chinese studies of impact of Bt crops on non-target arthropods

• The authors suggest which non-target species are most likely to be exposed to Bt proteins Plant Biotechnology Journal: Bt rice in China — focusing the non-target risk assessment

Chinese 90-day subchronic toxicity study with dicamba tolerant soybean MON87708 in rats finds no adverse effects Regulatory Toxicology and Pharmacology: A subchronic feeding study of dicamba-tolerant soybean with the dmo gene in Sprague-Dawley rats

Chinese three generation reproductive toxicity study with insect resistant rice expressing *Cry1Ac* and *sck* genes finds no adverse effects

Food and Chemical Toxicology: Three-generation reproduction toxicity study of genetically modified rice with insect resistant genes

Fall armyworms with resistance to Cry1F already widespread in western Bahia, Brazil, compromising usefulness of TC1507 corn

Pest Management Science: Frequency of Cry1F resistance alleles in Spodoptera frugiperda (Lepidoptera: Noctuidae) in Brazil

Study measures glyphosate conversion to AMPA in glyphosate tolerant and conventional canola

 The study found glyphosate tolerant canola rapidly converts glyphosate to AMPA, and that AMPA does not adversely affect the plant

Journal of Agricultural and Food Chemistry: Glyphosate-Resistant and Conventional Canola (Brassica napus L.) Responses to Glyphosate and Aminomethylphosphonic Acid (AMPA) Treatment

This report reflects personal views and not those of the U.S. Food & Drug Administration

For U.S. Government use only

Patrick Cournoyer, Ph.D.

Consumer Safety Officer

Center for Food Safety and Applied Nutrition Office of Food Additive Safety U.S. Food and Drug Administration

patrick.cournoyer@fda.hhs.gov











